

IRB UPDATE:
NOTIFICATION TO INVESTIGATORS
Effective January 1, 2003

SB 1614 - IRB is required to review death records research

In an effort to address identity theft, the California legislature passed Bill SB 1614, which requires vital statistics records, i.e., birth and death records, to be kept confidential and to be released only by request, signed under penalty of perjury, with proof of identity. Because the bill would have hampered research that allows death data containing identifying information to be released to university researchers. The author responded by including an exception for persons expressing a “valid scientific interest” as determined by an institutional review board (IRB).

The University of California Office of the President offers the following guidance in implementing the statute.

- To determine “valid scientific interest,” the IRB will consider whether the design of the study is consistent with sound scientific principles and ethical norms.
- When reviewing death data research, the IRB will take into account the intent of SB 1614 to permit public access to vital records while protecting personally identifiable information and the privacy of individuals to whom the information pertains.
- Death data research does not fall under the exemption at 45 CFR 46.101(b)(4) for research on publicly available existing data. Accordingly, such research will undergo expedited review under 45 CFR 46.110.
- The frequency of IRB review shall be left to the discretion of the IRB.

SB 1230 and SB 253 – Stem Cell Research

The California legislature in the most recent session passed two bills concerning human cloning and stem cell research.

SB 1230 removed a January 1, 2003, sunset date from an existing California law that prohibits any individual from engaging in human reproductive cloning. The bill, therefore, makes permanent the prohibition against human reproductive cloning.

SB 253 permits “research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source,

including somatic cell nuclear transplantation.” The bill further requires such research to be reviewed by an institutional review board (IRB). The bill addresses two additional items: Health care providers delivering fertility treatments shall give their patients information regarding donation of embryos for research purposes and embryonic or cadaveric fetal tissue may not be purchased or sold for research purposes.

Senate Bill 253 does not provide guidance on how stem cell research should be reviewed by institutional review boards. The bill states only that, “stem cell research ... raises significant ethical and policy concerns [which] must be carefully considered.” The bill relies, however on the recommendations of the California Advisory Committee on Human Cloning, which was established pursuant to 1997 state legislation that placed a temporary moratorium on human reproductive cloning. In its January 2002 report, Cloning Californians – Report of the California Advisory Committee on Human Cloning, the Advisory Committee recommended that California prohibit human reproductive cloning, and that the state permit and reasonably regulate human non-reproductive or therapeutic cloning. In reviewing stem cell research, the Advisory Committee recommended that the IRB be guided by the following:

- Acknowledgement that the human pre-embryo deserves “profound respect” but not the protection associated with full personhood.
- Egg donors and the donors of cells whose nuclei are transplanted must give “real and appropriate” informed consent.
- The benefits of human non-reproductive cloning must be distributed fairly, with particular attention paid to those consistently marginalized by the health care system.

The UC Office of the President suggests that each campus human subject protection program consider convening an ad hoc panel of relevant experts to review this research and provide analysis and recommendation to the IRB for use in the IRB’s review process.